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www.zlg.de
ZLG-BS-200.14.03



Product Service

EC Certificate

EC Design-Examination Certificate

Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD), Annex 2 (4)
(Other devices than custom made or intended for clinical investigation)

No. I7 039709 1067 Rev. 02

Manufacturer:

Medtronic Inc.

710 Medtronic Parkway N.E.
Minneapolis MN 55432
USA

Product:

**Implantable Cardiac Monitoring and
Recording Systems with a conditional
intended use in a MRI environment**

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with AIMDD Annex 2 (4). This design of the devices conforms to the requirements of this Directive. For marketing of these devices an additional Annex 2 certificate is mandatory. See also notes overleaf.

Report no.:

713156134

Valid from:

2019-10-21

Valid until:

2023-11-07

Date,

2019-10-21



Stefan Preiß

Head of Certification/Notified Body



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Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD), Annex 2 (4)
(Other devices than custom made or intended for clinical investigation)

No. I7 039709 1067 Rev. 02

Model(s): see below

Facility(ies):

Medtronic Inc.
8200 Coral Sea St., Mounds View MN 55112, USA

Medtronic Europe Sàrl
Route du Molliat 31, Case Postale, 1131 Tolochenaz,
SWITZERLAND

Medtronic Singapore Operations Pte. Ltd.
49 Changi South Avenue 2, Nasaco Tech Centre, Singapore
486056, SINGAPORE

Design Facility(ies):

Medtronic Inc.
8200 Coral Sea St., Mounds View MN 55112, USA

Parameters:

Clinical MRI systems with:

- a static magnetic field of 1,5T or 3,0T
- a max. spatial gradient of 25T/m
- a max. gradient slew rate performance per axis $\leq 200\text{T/m/s}$
- a whole-body SAR $\leq 4,0\text{W/kg}$
- a head SAR $\leq 3,2\text{W/kg}$

Product: Implantable Cardiac Monitoring and Recording Systems
(Implant)

Test Report No.: 713029780

Model:
Reveal LINQ

Model No:
LNQ11

Test Report No.: 713052876

Model:
Reveal LINQ insertion tools

Model No:
LNQTOOL

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ZERTIFIKAT • CERTIFICATE • CERTIFICADO • CERTIFIKAT • 認證證書

EC Certificate

EC Design-Examination Certificate

Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD), Annex 2 (4)

(Other devices than custom made or intended for clinical investigation)

No. 17 039709 1067 Rev. 02

Product: Application Software (external)

Test Report No.: 713030403

Model:	Model No:	for Programmer:	Implants to be programmed:
Application Software (external)	SW026	2090 and 29901	Reveal LINQ

Test Report No.: 713059729 / 713156134

Model:	Model No:	Implants to be programmed:
Reveal LINQ Mobile Manager App	MSW001	Reveal LINQ

Test Report No.: 713082131 / 713156134

Model:	Model No:	Implants to be programmed:
Reveal LINQ Mobile Manager App	MSW002	Reveal LINQ LINQ II

EC TYPE-EXAMINATION CERTIFICATE

Number: 2007841TE08

Directive 90/385/EEC on Active Implantable Medical Devices, Annex 3
(Other devices than custom made or intended for clinical investigation)

Manufacturer:

Medtronic Inc.
710 Medtronic Parkway NE
Minneapolis MN 55432
United States Of America

For the product / product category

Steroid eluting, bipolar, active, transvenous pacing lead

Documents, that form the basis of this certificate:

Certification Notice 2007841CN, initially dated 1 January 2001
Addendum, initially dated 14 June 2004

DEKRA hereby declares that the type of the product(s) falling within the product category mentioned above, fulfils the relevant provisions of 'Besluit Actieve Implantaten', the Dutch transposition of the Directive 90/385/EEC of 20 July 1990 concerning Active implantable medical devices, including all subsequent amendments, based on an examination in accordance with Annex 3 (4) of this Directive. The manufacturer has implemented a quality assurance system for the above mentioned product category in accordance to the provisions of Annex 3 (4) of Council Directive 90/385/EEC of 20 July 1990 and is subject to periodical surveillance.

The necessary information and the reference to the relevant documentation, of the products concerned and the examinations and assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 26 May 2024
Issued for the first time: 14 June 2004
Reissued: 1 July 2019

DEKRA Certification B.V.

Mrs. G.J. Zoetbrood
Managing Director

Ing. A.A.M. Laan
Certification Manager

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DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra-certification.com Company registration 09085396

ADDENDUM

Belonging to certificate: 2007841TE08

1/1

EC TYPE-EXAMINATION ACTIVE IMPLANTABLE MEDICAL DEVICES

Steroid eluting, bipolar, active, transvenous pacing lead

Issued to:

Medtronic Inc.
710 Medtronic Parkway NE
Minneapolis MN 55432
United States Of America

This certificate covers the following product(s):

CapSureFix™ Novus 4076
CapSureFix Novus MRI™ SureScan™ 4076

The product is designed in the facility:

Medtronic, Inc., 8200 Coral Sea Street, Mounds View, MN 55112, USA

EC Representative:
Medtronic B.V.
Earl Bakkenstraat 10
6422 PJ Heerlen
The Netherlands

Initial date: 14 June 2004

DEKRA Certification B.V.

Managing Director

Certification Manager

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T +31 88 96 83000 F +31 88 96 83100 www.dekra-certification.com Company registration 09085396



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EC Certificate

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Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD), Annex 2 (4)
(Other devices than custom made or intended for clinical investigation)

No. I7 039709 1199 Rev. 00

Manufacturer:

Medtronic Inc.

710 Medtronic Parkway N.E.
Minneapolis MN 55432
USA

EC-Representative:

Medtronic B.V.
Earl Bakkenstraat 10, 6422 PJ Heerlen, THE NETHERLANDS

Product:

Implantable Pacemaker Systems

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with AIMDD Annex 2 (4). This design of the devices conforms to the requirements of this Directive. For marketing of these devices an additional Annex 2 certificate is mandatory. See also notes overleaf.

Report no.:

713127272

Valid from:

2018-09-30

Valid until:

2023-09-29

Date, 2018-09-19



Stefan Preiß



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Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD), Annex 2 (4)
(Other devices than custom made or intended for clinical investigation)

No. I7 039709 1199 Rev. 00

Model(s):

see below

Facility(ies):

Medtronic Inc.

8200 Coral Sea St., Mounds View MN 55112, USA

Medtronic Puerto Rico Operations Co., Juncos
Road 31, Km. 24, Hm 4, Ceiba Norte Industrial Park, Juncos, PR
00777, USA

Medtronic Europe Sàrl
Route du Molliat 31, Case Postale, 1131 Tolochenaz,
SWITZERLAND

Medtronic Singapore Operations Pte. Ltd.
49 Changi South Avenue 2, Nasaco Tech Centre, Singapore 486056,
SINGAPORE

Design Facility(ies):

Medtronic Inc.

8200 Coral Sea St., Mounds View MN 55112, USA

Parameters:

./.

Implantable Pacemaker System: SureScan™

Product: Implantable Pacemaker

Test Report No.: 71350692

Model:

Advisa DR MRI™ SureScan™

Model No:

A3DR01

Variant:

MR Conditional

Test Report No.: 71366167

Model:

Ensura DR MRI™ SureScan™

Model No:

EN1DR01

Variant:

MR Conditional

Test Report No.: 713039269

Model:

Advisa SR MRI™ SureScan™

Ensura SR MRI™ SureScan™

Model No:

A3SR01

EN1SR01

Variant:

MR Conditional

MR Conditional

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Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD), Annex 2 (4)
(Other devices than custom made or intended for clinical investigation)

No. I7 039709 1199 Rev. 00

Product: Application Software (external)

Test Report No.: 71338901

Model:	Model No:	for Programmer:	Implants to be programmed:
Application Software (external)	SW005	2090	EnRhythm EMDR01

Test Report No.: 71351141

Model:	Model No:	for Programmer:	Implants to be programmed:
Application Software (external)	9995	2090	Advisa A3DR01

Test Report No.: 71368678

Model:	Model No:	for Programmer:	Implants to be programmed:
Application Software (external)	9995	2090	Ensura EN1DR01

Test Report No.: 713006624

Model:	Model No:	for Programmer:	Implants to be programmed:
Application Software (external)	SW018	2090	RevoMRI (US only)

Test Report No.: 713039234

Model:	Model No:	for Programmer:	Implants to be programmed:
Application Software (external)	9995	2090 29901	Advisa SR MRI SureScan A3SR01 Ensura SR MRI SureScan EN1SR01

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No. I7 039709 1199 Rev. 00

Product: Implantable Pacemakers

Test Report No.: 713095776

Model:	Model No:	Variant:
Percepta™ Quad CRT-P MRI SureScan™	W4TR04	MR Conditional
Serena™ Quad CRT-P MRI SureScan™	W4TR05	MR Conditional
Solara™ Quad CRT-P MRI SureScan™	W4TR06	MR Conditional
Percepta™ CRT-P MRI SureScan™	W1TR04	MR Conditional
Serena™ CRT-P MRI SureScan™	W1TR05	MR Conditional
Solara™ CRT-P MRI SureScan™	W1TR06	MR Conditional

Product: Application Software (external)

Test Report No.: 713095780

Model:	Model No:	for Programmer:	Implants to be programmed:
Application Software (external)	SW040	2090 29901	Percepta™ Quad CRT-P MRI SureScan™ W4TR04 Serena™ Quad CRT-P MRI SureScan™ W4TR05 Solara™ Quad CRT-P MRI SureScan™ W4TR06 Percepta™ CRT-P MRI SureScan™ W1TR04 Serena™ CRT-P MRI SureScan™ W1TR05 Solara™ CRT-P MRI SureScan™ W1TR06



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No. I7 039709 1199 Rev. 00

Product: Application Software

Test Report No.: 713095771

Model:	Model No:	for Programmer:	Implants to be programmed:
Azure / Astra Application Software	SW030	2090 29901	Azure™ XT DR MRI SureScan™ W2DR01 Azure™ S DR MRI SureScan™ W3DR01 Azure™ XT SR MRI SureScan™ W2SR01 Azure™ S SR MRI SureScan™ W3SR01 Astra™ XT DR MRI SureScan™ X2DR01 Astra™ S DR MRI SureScan™ X3DR01 Astra™ XT SR MRI SureScan™ X2SR01 Astra™ S SR MRI SureScan™ X3SR01

Product: Implantable Pacemakers

Test Report No.: 713095773

Model:	Model No:	Variant:
Azure™ XT DR MRI SureScan™	W2DR01	MR Conditional
Azure™ S DR MRI SureScan™	W3DR01	MR Conditional
Azure™ XT SR MRI SureScan™	W2SR01	MR Conditional
Azure™ S SR MRI SureScan™	W3SR01	MR Conditional
Astra™ XT DR MRI SureScan™	X2DR01	MR Conditional
Astra™ S DR MRI SureScan™	X3DR01	MR Conditional
Astra™ XT SR MRI SureScan™	X2SR01	MR Conditional
Astra™ S SR MRI SureScan™	X3SR01	MR Conditional



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No. I7 039709 1199 Rev. 00

Product: Implantable Pacemakers

Test Report No.: 713105247

Model:

Attesta™ DR MRI SureScan™
Attesta™ L DR MRI SureScan™
Attesta™ S DR MRI SureScan™
Attesta™ SR MRI SureScan™
Sphera™ DR MRI SureScan™
Sphera™ L DR MRI SureScan™
Sphera™ SR MRI SureScan™

Model No:

ATDR01
ATDRL1
ATDRS1
ATSR01
SPDR01
SPDRL1
SPSR01

Variant:

MR Conditional
MR Conditional
MR Conditional
MR Conditional
MR Conditional
MR Conditional
MR Conditional

Product: Application Software (external)

Test Report No.: 713105248

Model:

Application
Software

Model No:

SW043

For Programmer:

2090
29901

Implants to be programmed

Attesta™ DR MRI SureScan™
ATDR01
Attesta™ L DR MRI
SureScan™ ATDRL1
Attesta™ S DR MRI
SureScan™ ATDRS1
Attesta™ SR MRI SureScan™
ATSR01
Sphera™ DR MRI SureScan™
SPDR01
Sphera™ L DR MRI
SureScan™

SPDRL1
Sphera™ SR MRI SureScan™
SPSR01



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No. I7 039709 1199 Rev. 00

Product: Application Software (external)

Test Report No.: 713127914

Model:

CareLink SmartSync Azure
Astra App

Model No:

D00U003

**External Device Manager
System supported:**

CareLink SmartSync Device
Manager Patient Connector
24967